IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: DIGITEK
PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' REPLY TO DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL DEPOSITION TESTIMONY

Defendants' opposition brief is nothing more than a compilation of misdirection, fabrication, and underplay in a specious attempt to gain credence with the court and minimize its evasive discovery practices. Defendants' first response is to paint Plaintiffs' motion to compel deposition testimony as a backdoor motion to reconsider PTO Nos. 27 & 37. Second, Defendants' fabricate its candor and conduct evinced in depositions as cooperative and obliging. Finally, Defendants' unabashed endeavor to lessen the gravity of Mr. Richard Dowling's contradictions from his affidavit (Doc. 146) and his deposition testimony, which served as its basis to prevent the expansion of discovery, is unconvincing.

A. Defendants' Misdirection Tactics Cannot Veil Its Blatant Discovery Abuse

At the onset, Plaintiffs' reiterate that the instant pleading is a motion to compel deposition testimony pursuant to Federal Rule of Civil Procedure 37(a)(3)(B)(i), not a motion to reconsider PTO Nos. 27 & 37. In fact, Plaintiffs' motion seeks to compel Defendants from issuing repeated objections and directing deponents not to answer basic factual questions material to manufacturing and quality department practices and procedures at the Actavis

Totowa Facilities. Indeed, a vast majority of the questions Defense Counsel have instructed the witnesses not to answer involve violations of the cGMPs and the findings of the FDA inspections, which are paramount to Plaintiffs' allegations pled in their Master Complaint. Further, the conduct and information that is at issue here was not addressed in PTO Nos. 27 and 37. Plaintiffs have been dutifully proceeding and gathering facts as they became available. Many of the depositions were not scheduled until long after the time for reconsideration had lapsed. The simple fact remains that Defendants have controlled the pacing of depositions and the production of documents. Plaintiffs have worked as diligently as possible to cull through documents and proceed with depositions.

Likewise, Defendants' brazen effort to cast Plaintiffs' lawsuit as a fishing expedition because of the focus of the lawsuit has expanded from the recall letter, authored by Defendants, mentioning only "double-thick" Digitek® pills is unavailing. As both parties are acutely aware by this point in the litigation, "double-thick tablets" referenced in the Defendants' arguments is a red herring. While the suspension and recall of Digitek® for the presence of "double thick" pills was certainly a necessary step, it is by no means the sum total of the problems experienced at the plant. The violations found in the Digitek® manufacturing and quality areas were but a factor in the decision to suspend the remaining sixty-three product lines for numerous cGMP violations. In fact, Actavis Totowa Director of Manufacturing Operations Richard Dowling agreed in his deposition that the out-of-specification results observed by the FDA inspectors and released into commerce by Actavis Totowa throughout 2007 had nothing to do with physical double-thick pills, but instead referred to blend uniformity deficiencies. (Richard Dowling Dep., Dec. 16, 2009, at p. 159:9-24, 160:1-19, attached hereto as Exhibit A). Defendants have been aware of the Plaintiffs' position concerning this lawsuit since long before the Protective Order (PTO No.

12) was negotiated. This position was expressly stated at the November, 2008 Status Conference and during negotiations in January, 2009. The Master Complaint, which was filed the same week as the Protective Order, did not allege injury from double thick tablets. Rather, it clearly that "the amount of active ingredient was not consistent among Digitek® (Digoxin) tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label." (*See* Master Complaint, ECF # 73.) Once again, Defendants' venture to misdirect this court is unpersuasive.

B. PTO No. 12 is Limited to the Confidentiality of Discovery Information

Defendants continue to try to use PTO No. 12 as a shield to discovery. As stated in the Plaintiffs' initial brief, the very nature of a protective order is to keep information from reaching the public, not to prevent the free flow of information between the parties during discovery. In fact, PTO No. 12 has a section entitled "Scope of Order" that limits its reach. This section includes the purpose of the order, stating that "[d]isclosure and discovery activity in this proceeding may involve the production of confidential proprietary and private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted." (PTO No. 12, ECF # 71, p. 1, Section I(A).) Clearly, the information plaintiffs are seeking would be used for the purpose of prosecuting this litigation. Further, Plaintiffs are more than happy to give special protection from public disclosure for testimony that warrants such protection. The scope section further limits the reach by addressing the outer limits of the order. "This Protective Order does not confer blanket protections on all disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential." (*Id.* at p. 2, Section I(F).) This section clearly limits the

scope of PTO No. 12 to "the applicable legal principles for treatment as confidential" and NOT the limits of relevancy. While Defendants designation of over two million pages of discovery material as Confidential is already extensive, trying to extend this provision to limit what deponents can testify to is completely outside the intended scope of this order. Arguing in any way that PTO No 12 was to limit the scope of relevancy completely misrepresents the order and the negotiations that led to the order.

Plaintiffs agreed to the redaction section that allowed Defendants to initially redact information concerning other products. This provision was not meant to be the final word on relevance. It was added simply for the convenience of the parties and to allow Defendants to initially redact information that might not relate to the litigation. Clearly, Defendants are not the final arbiter of relevancy and their decision to redact does not give permanent protection to the underlying information. In fact, redactions are challengeable, just as any other abuse of discovery. Plaintiffs are currently working on challenging the thousands of pages contained of redactions in the redaction log.

C. Defendants' Fabricated Notion of Deposition Cooperation Strains Credibility

Defendants' argue that "Actavis has **always** allowed general questioning about manufacturing processes, GMPs, quality control, and quality assurance at the Actavis Totowa Facility, **and** with respect to Digitek®." Defs' Br. at 7. (emphasis added). If Actavis had **always** allowed Plaintiffs to perform unrestricted questioning of deponents of manufacturing processes, cGMPs, quality control, and quality assurance at the Actavis Totowa Facility, the instant motion would be unnecessary. The problem rests in the caveat "and with respect to Digitek®" because Defendants have treated the operative word "and" as if it should be omitted from the preceding sentence; which justifies the present relief requested. See id.

Defendants' contention that Plaintiffs' have been permitted to ask unconstrained questions regarding the manufacturing, production, cGMPs, quality control and quality assurance procedures and systems since they were uniform for all products manufactured at Actavis Totowa is simply false. See Defs' Br. at 7. During recurrent depositions in this litigation when such a question was posed by Plaintiffs' counsels' concerning uniform procedures in the manufacturing and/or quality departments, cGMPs, or observations of FDA inspectors, deponents were instructed to answer only to with respect to Digitek® or Plaintiffs were asked to rephrase with respect to Digitek® only. (See Additional Deposition Excerpts, Attached as Exhibit B). This practice reduces the quality and genuineness of the deponent's answer when Defendants' objection has zero bases because the question relates to general practices and procedures. Indirectly it constitutes witness coaching.

Nevertheless, by routinely objecting, asking Plaintiffs to rephrase, and directing deponents not to answer, Defendants have exploited and abused the scope of PTO Nos. 27 & 37. Ultimately, Defendants state that if Plaintiffs deposition questions were phrased properly under PTO Nos. 27 and 37, information sought in the present motion can be obtained. What this really means is that when Plaintiffs ask questions that Defendants want them to ask, which would have zero chance or likelihood of revealing anything substantive or germane, Defendants are content with not raising their repetitive PTO Nos. 12, 27, or 37 objections. Defendants' spurious impression that it has been cooperative and amenable to Plaintiffs' deposition questioning is derisory.

D. Mr. Dowling's Fallible Affidavit Casts Doubt on the Rationale Behind PTO No. 27

Defendants' strategy to combat Plaintiffs' evidence that Mr. Dowling's deposition testimony contradicts his affidavit supplied as the core of PTO No. 27 for the proposition that

Digitek® is unique and discovery into other pharmaceuticals would be irrelevant is to minimize the gravity of such an inconsistency. Though Mr. Dowling's contradictions are paramount to the discovery in this matter, Defendants attempt to clarify his testimony by pawning the obvious discrepancies as part of a "unique tooling" and as part of an overall "system." Interestingly, Mr. Dowling does not refer to Digitek's® production as a "system" anywhere in his affidavit.

To completely appreciate the complex falsities of Mr. Dowling's affidavit, a more in depth investigation is required. Again, during Mr. Dowling's deposition, a December 18, 2007 e-mail from Mr. Dowling to Bharat Patel and Apurva Patel entitled "new punches Digoxin" (Plaintiffs' Exhibit 97 to the deposition) exposed the following:

> As part of the corrective action for investigation number 07-093 for Digoxin double tablets, I am going to state that we buy a complete set of lowers and dies for both strengths of Digoxin that will be dedicated and not used for any other products. It is possible the tablet stuck to the punch and was double compressed.
>
> In addition, we should immediately do the same for the three strengths of – blank or redacted – right away.
>
> In the long run, the lower punches and dies will last longer if they are dedicated and not used for multiple products, and we won't have to delay set-ups because the lowers or dies needed are in use and not available

(Richard Dowling Depo., at 197:18-198:21). A few points can be divined from the foregoing: 1) new lower punches and new dies were needed to fix the problem with double compressing (twice the amount of digoxin) the Digitek® tablets; 2) these new lower punches and new dies will be exclusive to Digitek® production and not commingled with other products; 3) there was a similar problem warranting the identical solution for other products (redacted in production); 4) Actavis was experiencing durability issues with the previous Digitek® lower punches and dies because of interchangeable use with other products; and 5) accepting Mr. Dowling's advice will decrease set up time when producing Digitek®.

Again, Mr. Dowling's deposition testimony was:

> Q. Now, as of December 18, 2007, you did not have a set of lowers and dies that were dedicated solely to use to produce digoxin; isn't that right? …
> A. We had lower punches and dies as indicated in the production batch record available to use for digoxin….
> Q. Right. But the punches and dies were not reserved solely to use for digoxin were they?
> A. The lowers and dies were used interchangeably.
> Q. Okay. So when you say "interchangeably," you're saying that the lowers and dies were used for digoxin and for other products as well; isn't that right?
> A. Yes, they could be used for other products.
> Q. And what other products were they used for?
> A. That I don't recall. They would be products with the same die characteristic or size or the same punch or tablet configuration.

(Richard Dowling Depo., at 198:22-200:1). In addition to paragraph 14 of Mr. Dowling's affidavit where he states that "Digitek is produced using what effectively is a custom, Digitek-only press," other inconsistencies support Plaintiffs' position that Mr. Dowling's affidavit is unreliable. Indeed, Mr. Dowling avers that "[t]he manufacture of Digitek is a distinct process that involves a unique set of ingredients, specifications and **equipment**. (See Dowling Affidavit, June 22, 2009, ¶9, ECF # 146) (emphasis added). Likewise, "[t]he dies are custom designed to produce the correct size tablets, depending on dose strength, and **are used solely and exclusively to make Digitek**." *Id.* at ¶16 (emphasis added). In contrast, Mr. Dowling unequivocally admitted that the lower punches and dies were used interchangeably in his deposition. (Dowling Depo. at 199:9-13). In fact, he testified that the lower punches and dies used to make Digitek® could be used in a variety of products including products with the same die characteristic, size, same punch, or tablet configuration. (Dowling Depo. at 199:20-200:1)

Similarly, "[t]he punches are custom designed and are used solely and exclusively to make Digitek." Dowling Aff. at ¶17. Even if the upper punches, as Defendants' suggest, were exclusive to Digitek®, this information is not what Mr. Dowling represented in his affidavit and

it certainly does not make Digitek® a "unique system" as Defendant conveniently labels it. In reality, the "unique tooling" proffered by defendants includes dies and lower presses interchangeably used to produce other products with the same die characteristics, sizes, punches, and tablet configurations and an upper punch "unique" to Digitek® because it embosses the Digitek® emblem on the tablet.

Even accepting Defendants unique upper punch position as true, Mr. Dowling's deposition testimony is directly at odds with the affidavit relied upon by Magistrate Judge Stanley in issuing PTO No. 27 when she held "Mr. Dowling's affidavit states that the tools and dies used for tablet compression of Digitek are utterly unique." (PTO No. 27 at 131, citing Dowling Aff. at ¶¶ 14-22). Indeed, if only the upper punch is unique, then Mr. Dowling should have set forth that information in his affidavit instead of misleading information about two separate component parts that are not unique. The contradictions between Mr. Dowling's deposition testimony and his affidavit speak for themselves, plain and simple, Mr. Dowling's affidavit operates solely to limit discovery at the expense of the truth.

E. Conclusion

The testimony has revealed that indeed, Digitek® production was not unique to Digitek®, it was not produced in a vacuum, and the core of Defendants' arguments and consequential redactions are premised on falsehoods and half-truths; allowing Plaintiffs to ask questions pertaining to manufacturing and quality department practices and procedures without objection or direction not to answer is only logical. Further, as Plaintiffs' initial motion to expand discovery was limited in PTO Nos. 27 & 37 due to the unduly oppressive and costly burden on Defendants; unabated deposition testimony is both cost efficient and should impart zero burden on Defendants.

Simply put, the deposition testimony sought is relevant, related to the claims of the Plaintiffs and reasonably calculated to lead to the discovery of admissible evidence because the Actavis Defendants engaged in uniform practices and procedures in their Manufacturing and Quality Departments with Digitek® and other drugs. Further, Mr. Richard Dowling's Affidavit is unreliable and untrue nullifying the rationale of PTO #27. Consequently, Plaintiffs' respectfully requests this Court issue an Order granting their motion compelling certain deposition testimony.

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Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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